K123219

MAR 1 8 2013

5. 510(k) Summary

Premarket Notification Summary

1. Sponsor Information:

Laboratoires URGO
42 Rue de Longvic
21300 Chenove
France

Contact Person: Sophie Fortin
Regulatory Affairs Manager
Phone: +33.3.80.44.28.78
Fax: +33.3.80.44.71.40

2. Device Name:

Common or Usual Name: Absorbent Wound Dressing
Proprietary Name: Urgoclean Absorbent Wound Dressing
Classification Name: Dressing, Wound, Hydrophilic

3. Predicate Devices:

Aquacel® Hydrofiber® Wound Dressing (K982116, K063271, K080383), Convatec.

4. Description of Device

Urgoclean Absorbent Wound Dressing is a sterile non-woven highly absorbent pad coated with a soft-adherent lipido-colloid layer on the dressing/wound interface.
In contact with body fluids (exudates, slough) it forms a gel creating a moist environment, allowing a one piece and painless removal.
It is supplied sterile in an individual pouch.

5. Indications for Use

Urgoclean Absorbent Wound Dressing is indicated to manage all exuding wounds, especially during the debridement of slough. This includes chronic exuding wounds such as venous stasis ulcers, arterial ulcers, pressure ulcers (stage II-IV), diabetic ulcers; surgical wounds (post-operative, donor sites, dermatological); partial thickness burns; management of surgical or traumatic wounds that have been left to heal by secondary intention; local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided.

K123219

6. Description of Safety and Substantial Equivalence:

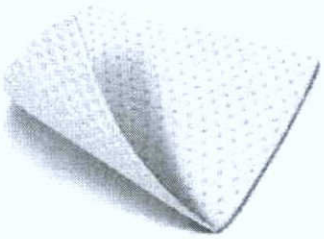
Safety Studies

Urgoclean Absorbent Wound Dressing is used for 1 to 2 days but may be replaced by the same dressing. It may therefore be employed for more than 30 days
Thus biocompatibility tests were conducted in accordance with standards ISO 10993 for a product considered as being in permanent contact with an altered surface (> 30 days):

- Cytotoxicity test
- Primary Skin Irritation test
- Sensitization test
- Genotoxicity tests: Bacterial reverse mutation study, chromosomal aberration study, Mouse bone marrow micronucleus study
- 28-day systemic toxicity study

Substantial Equivalence

Both products are fibers-based and have visually similar aspects:

Urgoclean Absorbent Wound Dressing	**Aquacel® Hydrofiber® Wound Dressing**
	

Moreover both products have similar properties & claims, leading to similar indications.

Key properties of both dressings are

- Absorption of exudates/body fluids by fibers => gel formation
- Creation of a moist environment to enhance healing , while avoiding maceration of peri-wound skin
- Non-sticking => pain-free removal
- Conformability to the wound
- Sterility

In addition Urgoclean Absorbent Wound Dressing can claim a possible "one-piece removal" due to its higher resistance / tensile strength.

K123219

When compared to Aquacel® Hydrofiber® Wound Dressing, it was demonstrated that Urgoclean Absorbent Wound Dressing have similar properties such as, both are made of sterile fibers and have comparable absorption and gelling properties leading to comparable indications for use.
Thus we conclude that Urgoclean Absorbent Wound Dressing and Aquacel® Hydrofiber® Wound Dressing are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Laboratoires Urgo
% Ms. Sophie Fortin
Regulatory Affairs Director
Excellence 2000
2 Avenue De Strasbourg
Chevigny Saint Sauveur, France 21801

March 18, 2013

Re: K123219
Trade/Device Name: Urgoclean Absorbent Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 07, 2013
Received: January 16, 2013

Dear Ms. Fortin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123219

Device Name: **Urgoclean Absorbent Wound Dressing**

Indications For Use:

- Urgoclean Absorbent Wound Dressing is indicated to manage all exuding wounds, especially during the debridement of slough. This includes chronic exuding wounds such as venous stasis ulcers, arterial ulcers, pressure ulcers (stage II-IV), diabetic ulcers; surgical wounds (post-operative, donor sites, dermatological); partial thickness burns; management of surgical or traumatic wounds that have been left to heal by secondary intention; local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123219